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Implementation of the 2011 Reimbursement Act in Poland: Desired and undesired effects of the changes in reimbursement policy☆

Paweł Kawalec[a,*], Anna Sagan[b], Ewa Stawowczyk[c], Iwona Kowalska-Bobko[a], Anna Mokrzycka[a]

[a] Jagiellonian University Medical College, Faculty of Health Science, Institute of Public Health, Poland
[b] European Observatory on Health Systems and Policies, United Kingdom
[c] StatSoft Polska Sp. z o.o., Poland

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ABSTRACT

The Act of 12 May 2011 on the Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Uses and Medical Devices constitutes a major change of the reimbursement policy in Poland. The main aims of this Act were to rationalize the reimbursement policy and to reduce spending on reimbursed drugs. The Act seems to have met these goals: reimbursement policy (including pricing of reimbursed drugs) was overhauled and the expenditure of the National Health Fund on reimbursed drugs saw a significant decrease in the year following the Act's introduction. The annual savings achieved since then (mainly due to the introduction of risk sharing schemes), have made it possible to include new drugs into the reimbursement list and improve access to innovative drugs. However, at the same time, the decrease in prices of reimbursed drugs, that the Act brought about, led to an uncontrolled outflow of some of these drugs abroad and shortages in Poland. This paper analyses the main changes introduced by the Reimbursement Act and their implications. Since the Act came into force relatively recently, its full impact on the reimbursement policy is not yet possible to assess.

1. Introduction

There is no homogeneous reimbursement policy in the European Union (EU). EU Member States are free to set their own lists of reimbursed drugs, their prices and reimbursement levels, as long as they comply with the overall EU regulations, such as the Transparency Directive [1,2]. The growth in public pharmaceutical expenditure (76% in the outpatient sector in the EU countries on average between 2000 and 2009) forced many European countries to introduce new pricing and reimbursement regulations aimed at reducing spending on drugs [2]. In Poland, spending on drug reimbursement by the public payer, the National Health Fund (NHF), saw a 12% growth in 2009 compared to 2008, which was the highest annual growth rate in the 2000–2011 period [3].

The Act on the Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Uses and Medical Devices [4] (hereinafter referred to as "the Reimbursement Act" or "the Act") was drafted by the Ministry of Health in order to rationalize the activity of the NHF in the field

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* Corresponding author. Tel.: +48 12 43 32 801
E-mail address: pawel.kawalec@uj.edu.pl (P. Kawalec).

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of reimbursement policy and to rationalize its budget (i.e. reduce its spending on reimbursed drugs). Another objective was to make prices of reimbursed drugs uniform across the country by introducing fixed prices and fixed wholesale and retail margins and to implement a new way of calculating them, which would comply with the EU accounting standards (Commission Regulation (EC) No 1126/2008 of 3 November 2008) and EU transparency regulations (mainly Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems [5] which recommends that reimbursement decisions are made on the basis of a credible assessment of data from the best available clinical trials and an assessment of clinical effectiveness and allows for experts' opinions to be additionally taken into account).

2. Policy content and process

The Reimbursement Act came into force on 1 January 2012 as part of a package of healthcare acts that also included: the Act on the Information Systems in Health Care, the Act on Patient Rights and the Patient Rights Ombudsman, the Act on the Professions of Physician and Dentist, and the Act on Therapeutic Activity. It laid down, in one legal act, the rules for the reimbursement of medicines, foodstuffs intended for particular nutritional uses, and medical devices. The key changes introduced by this Act are summarized in Table 1.

2.1. Pharmaceutical cost containment measures

In order to alleviate budgetary pressures, the Act introduced several mechanisms to decrease expenditure on reimbursed drugs: (1) the Act defined a percentage of the total funds for guaranteed benefits that can be used for drug reimbursement–this percentage was set at 17% (it used to be 18% or more); (2) when the amount spent on drug reimbursement exceeds 17%, all Marketing Authorisation Holders (MAHs) of the reimbursed drugs will have to cover the extra expenditure (a pay-back mechanism); (3) the Act made statutory prices based on mandatory negotiations, set price limits for generic drugs (set at 75% of the original drug price) and introduced adjusted fixed wholesale and retail margins (the pricing process for reimbursed drugs is depicted in Fig. 1). Before the introduction of the Act, there were no fixed prices for reimbursed drugs, which meant that access to reimbursed drugs was unequal. Prices had a character of maximum prices and pharmacies could charge lower prices to attract customers and increase sales. Pricing of generics was not regulated. The wholesale margin was relatively high compared to other European countries (8.91% in Poland compared to less than 5% in the Czech Republic, Greece, Spain, Finland, Italy, Sweden, and Latvia [6]) but manufacturers could offer rebates to pharmacies and this practice was widespread. There were also no fixed retail margins. The Reimbursement Act brought the wholesale margin down to 5% (from 2014 onwards), prohibited the use of rebates (pharmacies may now face financial penalties if they obtain rebates from the manufacturers), and made retail margin dependent on the wholesale price. The Act also prohibited advertising and other marketing of reimbursed drugs, which was previously not restricted (Table 1).

Another improvement introduced by the Reimbursement Act was the establishment of the Economic Committee, which is attached to the Ministry of Health and is responsible for negotiating with pharmaceutical companies the official sales prices for reimbursed drugs, levels of patient co-payments, and indications for reimbursement. The Economic Committee makes recommendations regarding: (1) the level of reimbursement (this can either be (a) 100% reimbursement with no patient co-payment, i.e. free of charge; (b) a flat fee; or (c) partial reimbursement – 70% or 50%), depending on the cost and duration of treatment; (2) differences in the reimbursement level, e.g. lower drug prices for certain population groups; and (3) reimbursement period (2, 3 or 5 years). According to the Act, reimbursement decision has to be made on the basis of scientific evidence. To have the drug reimbursed, the MAH has to prove its cost-effectiveness compared to the alternative therapeutic substance which is already reimbursed from public funds.

Another novelty of the Act in the area of reimbursement is the introduction of a negative reimbursement criterion, whereby reimbursement is waived when a health condition can be avoided by a change in lifestyle. This can lead to the exclusion of certain drugs, which could improve the quality of life for the patients, from reimbursement.

Under the provision of the Act, physicians were given additional obligations in terms of writing detailed prescriptions for reimbursed drugs, including specifying the reimbursement category. The NHF may impose heavy financial penalties if irregularities in prescribing (e.g. wrong level of reimbursement indicated on the prescription or writing a prescription for a reimbursed drug to a person not entitled for reimbursement) are detected.

2.2. Access to innovative high-cost drugs

The Reimbursement Act also introduced risk-sharing schemes (RSSs), which constitute a relatively novel mechanism for financing innovative medicines that are high-cost [7]. RSSs are mostly used when there is uncertainty about the cost-effectiveness of expensive, innovative drugs. During the health technology assessment (HTA) process a "threshold price" is calculated, i.e. the price at which the Incremental Cost-Effectiveness/Utility Ratio (ICER/ICUR) (the result of Cost-Effectiveness/Utility Analysis) does not exceed the threshold of three times per capita GDP. The MAH of the expensive drug may reduce the ICER/ICUR by proposing a risk-sharing scheme (RSS). It allows the distribution of financial and/or health outcomes risk between the MAH and the public payer [7]. In accordance with the Reimbursement Act [4] the proposed RSSs can (1) make the MAH's revenue dependent on the health outcomes (i.e. focus on the health effects); (2) make the official sales price dependent on the MAH assuring the supply of the drug at lower negotiated price (price discount); (3) make the official sales price dependent on the drug's turnover (price-volume agreement); (4) make the official sales price

Table 1
Reimbursement policy before and after 1 January 2012.

	2004–2011	From 2012
Governance and regulation		
Key legal acts	Act of 27 August 2004 on Healthcare Services Financed from Public Sources and the Act of 5 May 2001 on Pricing	Act of 12 May 2011 on the Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Uses and Medical Devices
Rules, conditions, and procedures for administrative decision making in the area of drug reimbursement		
Advisory body to the Ministry of Health	Drug Economy Task Force*	Economic Committee**
Decision-making and advisory body at the Agency for Health Technology Assessment	Consultative Council	Transparency Council for the President of the Agency for Health Technology Assessment***
Rules for assigning drugs to the particular reimbursement category		
Reimbursement limit groups (internal reference pricing)	Not used	Medicine with the same international name or different international name but with similar therapeutic effect and similar mechanism of action, with the same reimbursement indications and similar clinical effectiveness belong to the same limit group
Rules and procedures for setting the official sales prices for reimbursed drugs		
Prices of reimbursed drugs	Maximum prices; pharmacies can sell drugs at lower prices	Fixed prices; the same prices apply to all pharmacies
Prices of generic drugs	Not regulated	First generic drug on the list: 75% of original drug price; second and next generic drug on the list: price equal to the price of the cheapest medicine with the same active substance
Wholesale margin	8.91%	7% in 2012 6% in 2013 5% since 2014
Retail margin	Depends solely on the price of the drug	Calculated on the wholesale price of the product, being the basis for the limit in a given limit group
Publication of reimbursement list	Once or twice a year (irregularly); published as a regulation	Every 2 months; published as an announcement
Other cost containment measures		
Individual price agreements	Not used	Statutory prices are based on mandatory negotiations
Risk-sharing schemes (RSSs)	Not used	Yes; it is a mechanism which is used for financing innovative medicines that are high-cost and allows the distribution of financial and/or health outcomes risk between the Marketing Authorisation Holders (MAH) and the public payer
Percentage of the total funds for guaranteed benefits designed for drug reimbursement	18% or more	17%
Pay-back mechanisms	Not used	If the total amount spent on drug reimbursement exceeds 17%, all MAHs of the reimbursed drugs must cover the difference (excluding reimbursed drugs for which a RSS was agreed between the Ministry of Health and MAH)

Source: Authors' own compilation based on the legal acts cited in the Table.
* Consists of 3 representatives of the Ministry of Health, 3 representatives of the Ministry of Finance, 3 representatives of the Ministry of Economy.
** Consists of 12 representatives of the Ministry of Health and 5 representatives of the President of the National Health Fund.
*** Consists of 10 HTA experts, 4 representatives of the Ministry of Health, 2 representatives of the President of the National Health Fund, 2 representatives of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, 2 representatives of the Commissioner for Patients' Rights.

dependent on the MAH returning part of the reimbursement amount to the public payer (pay-back agreement); (5) set other reimbursement conditions which would increase access to the publicly guaranteed benefits or decrease their costs.

The Minister of Health recognizes the value of the RSSs and has been trying to incentivize pharmaceutical companies to enter into such schemes by offering them an exemption from the general payback scheme if they engage in RSSs instead. At the same time, companies may be fined by the Minister of Health if the agreed risk-sharing conditions are not met [7].

Apart from the RSSs, another mechanism aimed at increasing access to medicines is the mandatory bi-monthly reviews of the reimbursement lists. Before the introduction of the Act, reimbursement lists were updated irregularly, at most once or twice a year, which limited the timely introduction of new drugs.

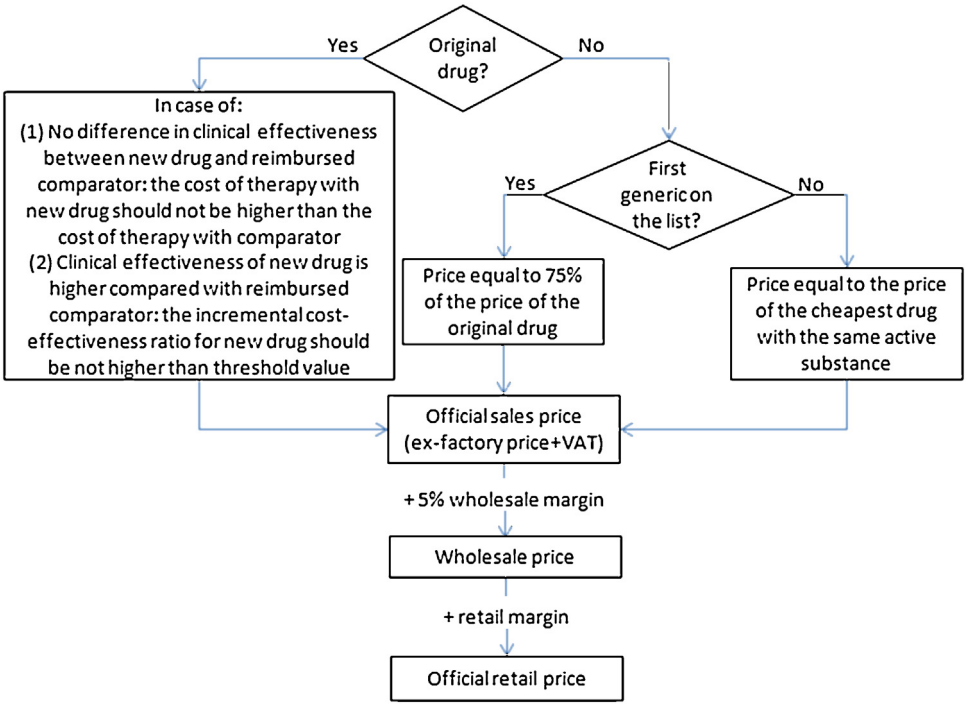

Fig. 1. Pricing of reimbursed medicines in Poland according to the 2011 Reimbursement Act.
Source: Authors.

3. Policy outcomes

3.1. Effects on the stakeholders

3.1.1. Effects on the public payer

According to the NHF, its expenditure on reimbursed ambulatory care drugs decreased significantly in 2012 by EUR 481 million compared to 2011 (a decrease of 22%) (Fig. 2) [1]. Since then, expenditure on ambulatory drugs has been growing at about 4.5–5.5% per year, which is slightly higher than the growth rates observed in 2010–2011 (3.6–3.7%). Before 2010, growth in spending on ambulatory drugs fluctuated highly from 0.6% in 2007 to 12% in 2009.

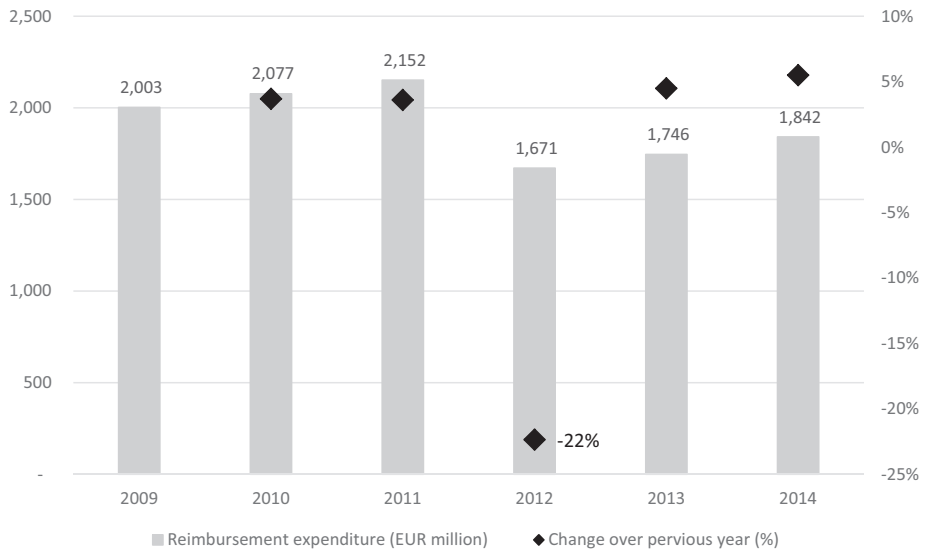

Fig. 2. Reimbursement expenditure of the NHF on ambulatory drugs, 2009–2014.
Source: Authors' own calculations based on NHF data [3] on the amount of refund.

The similar trend was observed in total NHF expenditure on the reimbursement of drugs, which decreased by EUR 438 million in 2012 (17%) compared to 2011. In 2013 and 2014, while increasing, total drug expenditure remained lower than the 2011 level (by EUR 339 million and EUR 74 million, respectively). Total spending on the reimbursed drugs grew by about 4.5% in 2013 and 11.5% in 2014. This means that the reduction in spending on reimbursed drugs was largely a one-off effect. This may be in part explained by the increased spending on therapeutic drug programmes (see below) and by the fact that the number of drugs reimbursed from the public funds in Poland has continued to grow. Between January 2012 and end of June 2014, 29 new original and 7 generic therapeutic substances were added to the reimbursement list [8]. Another 11 substances that had been available within a customized chemotherapy were also added to the reimbursement list. The number of items on the reimbursement list for ambulatory medicines increased from 2695 in January 2012 to 3743 in May 2015 [8].

The NHF also benefited from the introduction of the RSSs [3], although it is difficult to quantify these benefits as data on RSSs is not publicly available (neither the NHF nor the Ministry of Health publish such data in Poland and such data is also not available for other countries [7]). According to estimates by INFARMA (Employers' Associations of Innovative Pharmaceutical Companies), in 2012 and 2013, the total amount received by the NHF under the RSSs was EUR 76 million, which is much higher than the expenditure on reimbursing new innovative therapeutic substances that were added to the reimbursement list in those years which, according to the same source, amounted to EUR 3.4 million in 2012 and EUR 28.8 million in 2013 [9].

3.1.2. *Effects on the patients*

The implementation of the Reimbursement Act resulted in a significant decrease of the average retail price of reimbursed drugs and the average reimbursement limit. The latter means a higher level of patient co-payments, while the former has the opposite effect on the level of patient co-payments. In 2013, the level of patient co-payments for the reimbursed drugs was higher by EUR 0.04 compared to 2010. Between 2013 and 2014, the average patient co-payment decreased by EUR 0.18 compared to 2010, which means that reimbursed drugs have become more affordable to the patients in recent years [9]. In May 2015 the average level of co-payment was EUR 3.19, compared to EUR 3.68 in January 2012, i.e. a decrease of 24% [8]. However, the prices of non-reimbursed prescription drugs are still growing as does the overall amount of patient expenditure on drugs (for both reimbursed and non-reimbursed prescription drugs).

The Reimbursement Act also introduced substantial changes in the field of specialized therapies (mainly for oncology and severe chronic diseases). In 2012 and 2013, the NHF increased its expenditure on therapeutic drug programmes. Total NHF expenditure on medications used in therapeutic programmes or in chemotherapy increased by about 36% between 2012 and 2014 [3]. The number of patients treated within the existing therapeutic programmes increased from about 55,000 people (excluding customized chemotherapy) in 2011 to about 64,000 in 2013. In addition, 5000 people were treated under 13 new therapeutic programmes. At the same time, the number of patients covered by customized chemotherapy decreased [8,9].

Patients are also likely to have benefited from better access to innovative drugs and to drugs in general. This is mainly thanks to the RSSs, but also thanks to the more frequent updates of reimbursement lists (bi-monthly) and the introduction of penalties for pharmacies in case of failure to ensure the continuity of supply of reimbursed drugs.

The introduction of fixed official prices and margins for reimbursed drugs resulted in a reduction of their prices, and, as a consequence, Poland is one of EU countries with the cheapest drugs [9]. This caused outflow of drugs to other EU countries and shortages in Poland: pharmacies buy drugs from wholesalers or manufacturers at prices valid in Poland and sell them (via distributors) in Western European countries instead of selling them in Poland, as this is much more profitable. According to estimates, some 200 medications are missing, including insulin, anticoagulants, and drugs for Parkinson disease, cancer, and pulmonary diseases [10]. This parallel trade in reimbursed drugs is illegal and is prohibited under EU's directive on pharmaceutical trading (trade in other, i.e. non-reimbursed, drugs is allowed). This situation resulted in an ongoing protest of pharmacists who insist on guaranteeing equal access to reimbursed drugs [10].

3.1.3. *Effects on the physicians, pharmacies and manufacturers*

The effects on the other stakeholders are not well known. Physicians are likely to prescribe reimbursed drugs with greater caution and accuracy. Pharmacists are obliged to verify prescriptions and, in case of any concerns, must contact the supervisory bodies, i.e. the Main Pharmaceutical Inspectorate, and the NHF [1]. The profits of pharmacies and pharmaceutical companies are expected to decrease, following the introduction of fixed prices and margins, but to date there has been no reliable data allowing to verify this. The introduction of some expensive, innovative drugs to the reimbursement list by the NHF has the opposite effect and the total effect on the manufacturers' profits is difficult to gauge. The prohibition of advertising and other marketing of reimbursed drugs poses threat to the existence of smaller pharmacies. This may mean poorer access to drugs if these pharmacies are closed, but so far there is no evidence in this area.

3.2. *Effects on pharmaceutical regulation*

One of the undesired effects of the price reductions resulting from the Reimbursement Act, was the outflow of drugs abroad and their shortages on the Polish market (see Section 3.1). This motivated the government to take action. The amendment of the Act on Pharmaceutical Law, signed by the President on 21 May 2015, will significantly tighten the monitoring of drug availability and their export to other countries [8]:

- wholesalers and pharmacies will be obliged to inform the Main Pharmaceutical Inspectorate about the availability of drugs;
- based on the above information, the Minister of Health will publish the list of drugs that are likely to become unavailable in Poland;
- pharmacists will be obliged to inform the Main Pharmaceutical Inspector (within 24 h) about the lack of a reimbursed drug;
- the wholesaler that wants to export a drug with potentially limited availability will be obliged to inform the Main Pharmaceutical Inspectorate; the latter will have 30 days to object this;
- any refusal to order drugs will have to be justified by the wholesaler.

4. Conclusions

The implementation of the Reimbursement Act brought about numerous changes that affected the entire health care sector, including patients, physicians, pharmacists, public officials, and pharmacists.

The key effects were the economic benefits to the NHF (lower expenditure on reimbursed drugs) and patients (lower average spending on reimbursed drugs, though co-payments for certain drugs may be higher and the average spending on prescription drugs is higher [3], [8]). Patients also benefit from enhanced availability of new drugs but also suffer from shortages of certain drugs due to (illegal) reverse chain of drug distribution, which is the key unintended consequence of the Reimbursement Act. Medium and long-term effects of the Act on the expenditure on reimbursed drugs by both the NHF and the patients and on the access to drugs remain to be seen.

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